

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 85

**UNITED STATES PATENT AND TRADEMARK OFFICE**

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Ex parte WAYNE A. BORDER and  
ERKKI I. RUOSLAHTI

**MAILED**

**DEC 19 2002**

Appeal No. 2002-2285  
Application No. 08/349,479

PAT. & T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES

**ON BRIEF**

Before STONER, Chief Administrative Patent Judge; HARKCOM, Vice Chief Administrative Patent Judge; and WILLIAM F. SMITH, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

**DECISION ON APPEAL**

This is a decision in an appeal under 35 U.S.C. § 134 from the final rejection of claims 21 through 23 and 25, all the claims remaining in the application. The claims read as follows:

21. A method of decreasing the deleterious accumulation of extracellular matrix associated with a pathology or a condition wherein TGF- $\beta$ -induced production and deleterious accumulation of extracellular matrix in a tissue exists comprising:

contacting the tissue with an anti-TGF- $\beta$  antibody that binds to TGF- $\beta$ ;

whereby the binding of the anti-TGF- $\beta$  antibody to the TGF- $\beta$  suppresses the deleterious accumulation of the TGF- $\beta$ -induced extracellular matrix in the tissue.

22. The method of claim 21, wherein the pathology or condition is glomerulonephritis.

23. The method of claim 21, wherein the pathology or condition is selected from the group consisting of adult respiratory distress syndrome or cirrhosis of the liver.

25. The method of claim 21, wherein the condition is scarring.

The references relied upon by the examiner are:

Ruoslahti et al. (Ruoslahti)	5,583,103	Dec. 10, 1996
Dasch et al. (Dasch)	5,772,998	Jun. 30, 1998

Bassols et al. (Bassols), "Transforming Growth Factor  $\beta$  Regulates the Expression and Structure of Extracellular Matrix Chondroitin/Dermatan Sulfate Proteoglycans," J. Biol. Chem., Vol. 263, pp. 3039-3045 (1988)

Claims 21, 23, and 25 stand rejected under 35 U.S.C. § 102(e) on the basis of Dasch. Claims 21 and 22 stand rejected under 35 U.S.C. § 103. The examiner relies upon Dasch, Ruoslahti, and Bassols as evidence of obviousness. We affirm but denominate our affirmance as a new ground of rejection under 37 CFR § 1.196(b).

#### Discussion

The sole issue to be resolved in this appeal is stated by appellants as follows:

Appellants traverse both of the above-mentioned grounds for rejection on the basis of prior invention of the claimed subject matter vis-a-vis the effective filing date of the Dasch et al. patent. In particular, Appellants maintain that the Declaration under 37 C.F.R. § 1.131, filed on March 15, 2001, which is attached as appendix C, sufficiently shows Appellants prior invention to antedate Dasch et al., which is attached as Appendix D.  
Appeal Brief, Paper No. 80, page 6.

In other words, if Dasch is available as prior art to the claims on appeal, appellants lose.

In considering this issue, we find that both appellants and the examiner have overlooked a threshold issue which is dispositive of the appeal, i.e., are the provisions of 37 CFR § 1.131 available under the facts of this case.

Rule 131 states that prior invention may not be established under this rule if "[t]he rejection is based upon a U.S. patent . . . to another or others which claims the same patentable invention as defined in § 106.01(n) . . ." In our view, the claims on appeal and the claims of Dasch are directed to the same patentable invention. Thus, the provisions of 37 CFR § 1.131 are not available to appellants in this case.

Claim 1 of Dasch reads as follows:

1. A method for neutralizing the inhibitory effects of transforming growth factor beta (TGF- $\beta$ ), which method comprises administering a therapeutically effective amount of a monoclonal antibody that neutralizes transforming growth factor- $\beta$ 1 and transforming growth factor- $\beta$ 2.

As can be seen, both methods are directed to neutralizing TGF- $\beta$  through use of an anti-TGF- $\beta$  antibody. The present method is useful in treating cirrhosis of the liver and scarring. See claims 23 and 25. These two conditions are also treatable by the method described in Dasch. See column 5, lines 36-45. The claims of Dasch require the use of a monoclonal antibody that neutralizes TGF- $\beta$ 1 and TGF- $\beta$ 2. The antibodies of the present invention may be monoclonal. Specification, page 8, lines 35-36.

Appellants explain that their use of the term "TGF- $\beta$ " is meant to include all modifications of TGF- $\beta$ , including TGF- $\beta$ 1 and TGF- $\beta$ 2. Specification, page 10, lines 4-11. See also page 20, lines 19-20 ("it is expected that the antibodies would also inhibit TGF- $\beta_2$ .").

Under these circumstances, the issue of priority of invention cannot be resolved through use of a declaration under 37 CFR § 1.131 but, rather, only through an interference proceeding, if otherwise appropriate.<sup>1</sup>

Since this threshold issue has not been satisfied, we need not reach the merits of appellants' showing under 37 CFR § 1.131. For these reasons, we find ourselves in agreement with the examiner's conclusion that the claims on appeal are unpatentable on the basis of Dasch. However, since our reasons differ substantially from those of the examiner, we will denominate our affirmance a new ground of rejection under 37 CFR § 1.196(b).

Time Period for Response

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b). 37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

- (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .

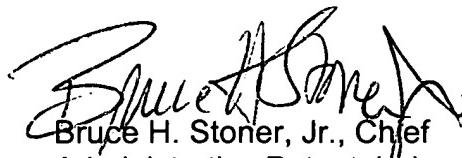
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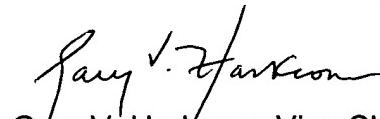
<sup>1</sup> For example, in considering whether an interference proceeding is appropriate, the examiner and appellants will have to consider the requirements of 35 U.S.C. § 135(b) and 37 CFR § 1.608(b).

(2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED- 37 CFR § 1.196(b)

  
Bruce H. Stoner, Jr., Chief  
Administrative Patent Judge

  
Gary V. Harkcom, Vice Chief  
Administrative Patent Judge

  
William F. Smith  
Administrative Patent Judge

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